

THE UNITED STATES PATENT AND TRADEMARK OFFICE Re: Appeal to the Board of Appeals

In re Ap	plicatio	n of)		
HEINZ 6	et al.)	Art Unit:	1636
Serial N	Ο.	10/019,048)	Examiner:	AKHAVAN, Ramin
Filed:		December 27, 2001)		
For:			ANTS A	ND A PROC		FAS-CONTAINING OILS HE PREPARATION OF
To: Hor	n. Com	missioner of Patents	and Tra	demarks		
2. [3. [4. [he ded] A ch X] <u>BRI</u>] An C	FICE OF APPEAL: A sision dated on the extension dated on the extension appeal in this prained that the properties of the prope	of the Pri ension fe applicati sted. fee of \$2 paid in p	Service as first class Trademarks, Washing January 18, 2004 Date of Deposit Sabine Berg Person Making Deposit Signature hereby appear imary Examin se of \$ is on is transmit 280.00 is enclo	mail in an envelope ad ton, D. C. 20036, on: it als to the Boarder finally reject enclosed. ted herewith. osed.	ng deposited with the United States Postal dressed to Commissioner of Patents and described to Commissioner of Patents and described to Gamma desc
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Washington, D.C. 20036 (202) 659-0100 HBK/sb

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the application of) MAIL STOP APPEAL BRIEF HEINZ et al. Group Art Unit: 1636 Serial No. 10/019,048 Examiner: Akhavan, Ramin Filed: March 20, 2001

PLANTS EXPRESSING A6-DESATURASE GENES PUFAS CONTAINING OILS For:

FROM THESE PLANTS AND A PROCESS FOR THE PREPARATION OF

UNSATURATED FATTY ACIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, PO Box 1450, Alexandria, VA 22313-1450, on:

January 18, 2005 Date of Deposit Sabine Berg Person Making Deposit Signature

Honorable Comm'r. of Patents PO Box 1450 Alexandria, VA 22313-1450

BRIEF ON APPEAL

Sir:

This appeal is from the examiner's final office action of July 13, 2004.

REAL PARTY IN INTEREST

The real party in interest is BASF Aktiengesellschaft, of Ludwigshafen, Germany. Reel/Frame012552/0033, recorded on December 27, 2001.

RELATED APPEALS AND INTERFERENCES

To appellants' knowledge and belief, there are no interferences or other appeals which will directly affect or be directly affected by or have a bearing on the Board's

decision in this application. 01/26/2005 MAHMED1 00000073 110345 10019048

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STATUS OF THE CLAIMS

Claims 1-12 currently are pending in the application. Claims 11 and 12 have been withdrawn from consideration by the examiner.

STATUS OF THE AMENDMENTS

The claims have not been amended subsequent to the final office action.

SUMMARY OF THE INVENTION

The present invention relates to an improved process for the preparation of unsaturated fatty acids and to a process for the preparation of triglycerides with an increased content of unsaturated fatty acids. The invention relates to the generation of a transgenic organism, preferably of a transgenic plant or of a transgenic microorganism, with an increased content of fatty acids, oils or lipids with $\Delta 6$ double bonds owing to the expression of a moss $\Delta 6$ -desaturase. The invention furthermore relates to transgenic organisms containing a $\Delta 6$ -desaturase gene, and to the use of the unsaturated fatty acids or triglycerides with an increased content of unsaturated fatty acids which have been prepared by the process.

(Specification, page 1, lines 6-19).

ISSUES

Whether claims 1-10 are comply with the written description requirement of 35 USC § 112, first paragraph.

GROUPING OF CLAIMS

The claims have not been argued separately.

<u>ARGUMENT</u>

The following legal authorities are relied on in the following arguments in the order in which they are cited:

In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)

REJECTIONS

Claims 1-10 are rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. The examiner believes the specification does not contain any examples of sequences that have said homology and have the prescribed activity. Even though the claims have functional limitation which is that the derivative must have a minimal level of $\Delta 6$ -desaturase activity, the examiner believes applicants merely limit 85% homologous regions to a functional limitation and said sequences have not been clarified.

An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Applicants believe the present application meets the above requirement. This is because what is necessary is a suitable method, e.g., a computer algorithm, for determining whether a sequence has the recited degree of sequence homology. Such algorithms or default parameters are available to one of ordinary skill in the art. An example is the algorithm of Karlin and Altschul (Proc. Natl.

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Acad. Sci. USA 87: 2264-2268, 1990). A definitive method for identifying nucleic acids that have the recited percent homology to the referenced sequences are available.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that reversal of the examiner's rejection of all claims is in order.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

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APPENDIX

- A process of preparing unsaturated fatty acids, which comprises introducing, into an organism, at least one isolated nucleic acid sequence encoding a polypeptide having Δ6-desaturase activity, selected from the group consisting of:
 - a) A nucleic acid sequence having the sequence shown in SEQ ID NO: 1,
 - b) nucleic acid sequences which, as a result of the degeneracy of the genetic code, are derived from the sequence shown in SEQ ID NO: 1,
 - c) derivatives of the nucleic acid sequence shown in SEQ ID NO: 1 which encode polypeptides with the amino acid sequences shown in SEQ ID NO: 2 and have at least 85 homology at the amino acid level without substantially reducing the enzymatic action of the polypeptides,

and culturing this organism, where the cultured organism contains at least 1 mol% of unsaturated fatty acids based on the total fatty acid content in the organism.

- 2. The process as claimed in claim 1, wherein the nucleic acid sequence is derived from a plant or algae.
- 3. The process a claimed in claim 1, wherein the nucleic acid sequence is derived form Physcomitrella patens.

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- 4. The process as claimed in claim 1, wherein the organism is an organism selected from the group consisting of bacterium, fungus, ciliate, algae, cyanobacterium, animal or and plant.
- 5. The process as claimed in claim 1, wherein the organism is a plant or algae.
- 6. The process as claimed in claim 1, wherein the organism is an oil crop.
- 7. The process as claimed in claim 1, wherein the cultured organism contains at least 5% by weight of unsaturated fatty acids based on the total fatty acid content in the organism.
- 8. The process as claimed in claim 1, wherein the unsaturated fatty acids are isolated from the organism.
- 9. A transgenic organism selected from the group consisting of plants, fungi, ciliates, algae, bacteria, cyanobacteria and animals comprising at least one isolated nucleic acid sequence encoding a polypeptide with Δ6-desaturase activity, selected from the group consisting of:
 - a) A nucleic acid sequence having the sequence shown in SEQ ID NO: 1,
 - b) nucleic acid sequences which, as a result of the degeneracy of the

- genetic code, are derived from the sequence shown in SEQ ID NO: 1,
- derivatives of the nucleic acid sequence shown in SEQ ID NO: 1 which encode polypeptides with the amino acid sequences shown in SEQ ID NO: 2 and have at least 85 homology at the amino acid level without substantially reducing the $\Delta 6$ -desaturase action of the polypeptides,
- 10. A transgenic organism as claimed in claim 9, wherein the organism is a plant or algae.
- 11. An oil, lipid or fatty acid or fraction thereof, prepared by the process as claimed in claim 1.
- 12. The use of the oil, lipid or fatty acid composition as claimed in claim 11 or of a transgenic organism in feed, foodstuffs, cosmetics or pharmaceuticals.